

REMARKS

At the outset, Applicants would like to thank Examiners Nelson and Kubelik for taking the time to discuss the issues relating to this case in a telephonic interview. Specifically, Applicants take exception to the requirement to elect a single fusion protein encoding sequence. Examiner Nelson suggested provided an alignment of the fusion proteins claimed in claim 11 to demonstrate the similarity and near identity of the sequences claimed. The aforementioned alignments are submitted herewith. Given the similarity between the sequences encompassed by claim 11, Applicants request that the requirement to elect a single species for prosecution be withdrawn.

The obviousness rejection based on the combination of Wilcox and Horn was also discussed. The Examiners indicated that they would have to study the disclosure of Wilcox more closely to determine whether the pesticidal fusions encompassed by the present claims are rendered obvious by the disclosure of the intermediate hybrid molecules described in Examples 1, 2 and 3 of Wilcox. Applicants respectfully submit, based on the remarks set forth below, this inquiry must be answered in the negative.

At page 3 of the Official Action, the Examiner has objected to claims 16, 20, 24, 25, 26, and 32 for containing certain minor informalities. The claims have been amended to in keeping the Examiner's helpful suggestions thereby rendering these objections moot.

Claims 1-3, 5, 7-10, 12-32, and 43-47 stand rejected under 35 U.S.C. §112, first paragraph as allegedly encompassing subject matter which was not enabled by the specification as filed. The Examiner has further rejected the foregoing claims under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement.

The Examiner has rejected claims 1-16, 19-32, and 42-47

under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The allegedly ambiguous language has been eliminated from the claims thereby rendering these rejections moot.

At page 12 of the Official Action, the Examiner has rejected claims 1-3, 7-10, 12-16, 20-22, 43 and 44 under 35 U.S.C. §102(b) as allegedly anticipated by US Patent 5,668,255 to Murphy et al. taken with evidence of US Patent 4,664,911 to Uhr et al.

Claims 1-3, 7-10, 12-23, 26, 27, 31, 32, 43 and 44 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by US Patent 5,290,914 taking with the evidence of Crickmore et al. and US Patent 4,664,911 to Uhr et al.

At page 15 of the Official Action, the Examiner has rejected claims 1-3, 5-23, 26, 27, 31, 32, and 42-45 under 35 U.S.C. §103(a) as allegedly being obvious over US Patent 5,290,914 to Wilcox et al. in view of US Patent 5,538,868 to Horn et al.

Claims 24, 25, 28-30, 46 and 47 stand rejected as allegedly obvious over Wilcox in view of Horn et al. as applied to claims 1-3, 5-23, 26, 27, 31, 32 and 42-45 above and further in view of Gordon-Kamm et al.

Claim 11 has been amended such that it is now an independent claim. The remaining claims depend directly or indirectly from claim 11. Inasmuch as claim 11 was not rejected under 35 U.S.C. §102, it is submitted that the above-mentioned §102 rejections are no longer appropriate and should be withdrawn. As mentioned above, the rejection of claim 11 under 35 U.S.C. §103 will be addressed hereinbelow.

Pending claims 1-10 14, 15, and 42 have been canceled. The cancellation of the last mentioned claims should not be construed as indicative of Applicants concurrence or acquiescence in the various rejections thereof as set forth in the September 22, 2004 Official Action, or otherwise as an

abandonment of Applicants efforts to secure patent protection on the subject matter of those claims. To the contrary, Applicants vigorously dispute those grounds of rejection. Such arguments as Applicants have to advance in rebuttal, however, are being reserved for a continuing application, should one be filed and will include claims directed to some or all of the subject matter of the canceled claims.

Applicants respectfully submit that the claims as presently amended are in condition for allowance. Each of the above-noted objections and rejections under 35 U.S.C. §112, first and second paragraphs, §102 and §103 is, therefore, respectfully traversed.

**THE SUBJECT MATTER OF CLAIMS 11, 13, 16-32, AND 43-47 AS
AMENDED IS FULLY ENABLED AND DESCRIBED IN
THE SPECIFICATION AS FILED**

The claims have been amended to recite the pesticidal fusions encompassed by claim 11. The Examiner has acknowledged that the subject matter of claim 11, namely pesticidal fusions comprising the CryIA(b) or CryIA(c) toxin domains from Bt fused to the lectin domain from ricin (e.g., RTB1, RTB2 and RTB3), vectors encoding the same, host cells and plants comprising said pesticidal fusions are enabled and described in the application. Accordingly, Applicants submit that the present claims satisfy all of the requirements of 35 U.S.C. §112, first paragraph.

**CLAIMS 11, 13, 16-32, AND 43-47 AS AMENDED ARE NOT RENDERED
OBVIOUS OVER THE DISCLOSURE OF US PATENT 5,290,914 TO WILCOX
IN VIEW OF US PATENT 5,538,868 TO HORN ET AL.**

The criterion for determining obviousness under §103 is whether the prior art supplies some motivation or incentive to

one of ordinary skill in the art to arrive at the invention as claimed. In re Dow Chemical Company, 5 U.S.P.Q. 2d 1929 (Fed. Cir. 1988). Obviousness cannot be established by combining teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. In re Fine, 5 U.S.P.Q.2d (Fed. Cir. 1988). Moreover, the teaching or suggestion supporting the desirability or the combination must be found in the prior art, not in applicant's disclosure. In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). Under these standards, neither of the cited references, considered singly or in combination, render obvious the invention as claimed in claims 11, 13, 16-32 and 43-47 as amended.

Before addressing obviousness rejection raised by the Examiner, Applicants wish to clarify the interpretation of the disclosure of Wilcox. The Examiner alleges that Wilcox discloses a pesticidal fusion between a lectin and a toxin. This is a misunderstanding of the teaching of Wilcox. Wilcox actually only discloses fusions between a toxin and a **non-lectin** binding domain. Some of the confusion may arise partly because the toxins used in Wilcox and in the invention occur naturally as associations between a toxin and a binding domain. For example Diphtheria occurs as the toxic A chain and a B chain. Ricin occurs as a toxic A chain and a non-toxic B chain and Bt occurs as a toxin domain and a non-lectin binding domain. Despite the Examiner's reliance on Uhr et al. (1987), there is a considerable body of scientific evidence which refutes the assertion that Dt contains a lectin binding domain. Indeed, DT has a specific receptor, pro-HB EGF. It does not bind non-specifically to cell membranes in a manner comparable to the ricin lectin domain and it cannot be competed off cells with excess sugar as ricin can.

Wilcox uses fusions between a toxin and a non-lectin binding domain. He suggests using DTA or ricin A as the toxin and Bt as the binding domain. In contrast to Wilcox, the

claimed invention relates to fusions between a toxin and lectin binding domain, now limited to fusions between Bt and RTB as specified in the claim.

The Examiner erroneously states that Wilcox makes constructs in which the Diphtheria B chain is used for binding (examples 1 and 2). However, a close reading of the specification reveals that the Diphtheria B chain is not used for binding in the constructs of Wilcox. Examples 1 and 2 describe the preliminary cloning steps to produce constructs from which Bt-**DTA** fusion is subsequently produced. The nucleic acids in these examples are only intermediate products, not the fusions taught for use as pesticidal fusions by Wilcox. The overall teaching of Wilcox is to fuse a toxin with a specific binding domain (Bt is exemplified) , not a lectin, and it is this type of construction that is produced by the methods described in the examples (see example 3 which follows on from examples 1 and 2). Column 1 lines 39-55 of Wilcox explain that

"The subject invention concerns novel hybrid pesticidal toxins. Specifically exemplified is an insecticidal infusion protein expressed as a single polypeptide product of a hybrid gene comprising a cytotoxic agent and **a specific insect gut cell recognition (binding) protein to direct the cytotoxic agent to the host target.** Details for the construction of a hybrid Bt toxin are disclosed. The cytotoxic agent is an ADP ribosylating enzyme. For example, the cytotoxic agent can be a fragment of diphtheria toxin, plus the B fragment of the Diphtheria toxin **which has been truncated at the carboxyl terminus to remove the eukaryotic binding region.** The Diphtheria toxin gene 3' recognition domain is replaced with a synthetic DNA linker region to which a gene encoding the insect gut epithelial cell recognition portion of *Bacillus thuringiensis* var. *kurstaki* HD-73 is ligated.' (Emphasis

added)

Thus, contrary to the Examiner's assertions, the Diphtheria toxin B domain is not used as a binding agent in these fusions. Instead, it has merely a transient presence before being truncated to remove the binding region of DTB. This is shown in Example 3 where truncated DTB fusion is constructed from the starting materials produced in examples 1 and 2 (column 22, lines 52-57). In other words, the constructs of examples 1 and 2 have a DTB domain that is then **replaced** by a Bt binding domain, which is not a lectin. Thus the **end product** is a fusion between a toxin and a specific non-lectin binding domain. While there is a suggestion that different cytotoxic agents may be substituted for DTA, there is no teaching in Wilcox whatsoever to substitute different binding domains for the Bt binding domain actually utilized.

In order for an obviousness rejection to stand, the overall teaching of the document must be considered, not isolated examples taken out of context. The preliminary materials and steps used by Wilcox in examples 1 and 2 are not an appropriate starting point for an obviousness attack on the claimed subject matter, as there is no teaching or suggestion in Wilcox that would lead the skilled person to isolate these intermediate products and use them to construct the fusions of the claimed invention. The materials in examples 1 and 2 are only disclosed for use in the subsequent example 3 in which the DTB domain is replaced.

To construct pesticidal fusions in which the binding domain is a lectin, the skilled person would have to disregard the overall teaching of Wilcox and use the constructs of examples 1 and 2 in a new and unsuggested manner. Neither Wilcox nor any of the other cited art provides the motivation for the skilled person to do so. Therefore, the claimed subject matter is inventive.

It is the Examiner's position that the invention is obvious over a combination of Wilcox and Horn. However, there

is no motivation for the skilled person to combine Wilcox with Horn or to use the ricin B chain as an alternative to the diphtheria toxin B chain in the pesticidal fusions. This is because in Wilcox the diphtheria toxin B chain is not used as a binding domain - it is only an intermediate domain, which is later replaced by a specific binding domain isolated from Bt.

To support her position, the Examiner relies on column 3, lines 9-16 of Wilcox, which discloses that alternative **cytotoxic agents** may be used instead of the exemplified diphtheria toxin A domain. There is no teaching in Wilcox or any of the cited art whatsoever to substitute the Bt cell binding domain which binds specifically to a molecule within the insect gut with a lectin domain which binds non-specifically to cells, (e.g., the RTB domains as taught in the claimed invention). Indeed, based on this suggestion, the skilled person would be lead to use intact ricin or the ricin A chain fused to a binding domain specific for a host cell target. In other words, carrying out the suggestions of Wilcox in this passage would only produce fusions between the various alternative toxins disclosed and a non-lectin binding domain with specificity for a host cell target. Inasmuch as the present claims are directed to pesticidal fusions which lack the cytotoxic domain of ricin, it is submitted that this passage actually teaches away from what applicants have done. Given the suggestion to use cytotoxic ricin (which requires the presence of the A chain), it is further submitted that Horn fails to supplement the deficiencies of Wilcox as the Horn patent is directed to the cloning of the ricin B chain in the absence of the A chain.

Finally, Applicants note that claim 11 is drawn to pesticidal fusions having expressly recited sequences. None of these particular fusion sequences are taught in Wilcox or Horn. It is a well-settled premise in patent law that "silence in a reference is not a proper substitute for adequate disclosure of facts from which a conclusion of obviousness may

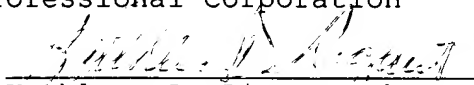
justifiably follow". In re Burt, 148 U.S.P.Q. 548 (CCPA 1966)

In light of the foregoing, Applicants submit that the Examiner has failed to establish a prima facie case of obviousness of the subject matter of claim 11 as amended and claims dependent therefrom. It is clear that the expressly disclosed nucleic acids are inventive over the prior art. As these nucleic acids are a feature that runs through all the claims, all the claims are inventive. Accordingly, Applicants request that the rejection of claims 11, 13, 16-32 and 43-47 under 35 U.S.C. §103 be withdrawn.

It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. The claims as presently amended are also believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments and remarks presented herein, it is respectfully urged that the rejections set forth in the September 22, 2004 Official Action be withdrawn and that this application be passed to issue. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By 
Kathleen D. Rigaut, Ph.D., J.D.
PTO Registration No. 43,047

Telephone: (215) 563-4100
Facsimile: (215) 563-4044
Enclosures: Table listing % identity of pesticidal fusions
encompassed by claim 11
Alignment of pesticidal fusions claimed

Table 1. Percentage identity between aligned sequences.

Alignment number	Sequences Aligned			% Identity
1	CryIA(b)-RTB1	Vs	CryIA(b)	73
2	CryIA(b)-RTB3	Vs	CryIA(b)	83.9
3	CryIA(c)-RTB1	Vs	CryIA(c)	73.5
4	CryIA(c)-RTB3	Vs	CryIA(c)	83.9
5	CryIA(b)-RTB1	Vs	CryIA(b)-RTB2	96.6
6	CryIA(b)-RTB1	Vs	CryIA(b)-RTB3	87.4
7	CryIA(b)-RTB1	Vs	CryIA(c)-RTB1	91.8
8	CryIA(b)-RTB1	Vs	CryIA(c)-RTB2	88.4
9	CryIA(b)-RTB1	Vs	CryIA(c)-RTB3	79.3
10	CryIA(b)-RTB2	Vs	CryIA(b)-RTB3	90.5
11	CryIA(b)-RTB2	Vs	CryIA(c)-RTB1	88.4
12	CryIA(b)-RTB2	Vs	CryIA(c)-RTB2	91.5
13	CryIA(b)-RTB2	Vs	CryIA(c)-RTB3	82.5
14	CryIA(b)-RTB3	Vs	CryIA(c)-RTB1	79.3
15	CryIA(b)-RTB3	Vs	CryIA(c)-RTB2	82.1
16	CryIA(b)-RTB3	Vs	CryIA(c)-RTB3	90.6
17	CryIA(c)-RTB1	Vs	CryIA(c)-RTB2	96.6
18	CryIA(c)-RTB1	Vs	CryIA(c)-RTB3	87.4
19	CryIA(c)-RTB2	Vs	CryIA(c)-RTB3	90.5
20	CryIA(b)	Vs	CryIA(c)	88.9
21	CryIA(b)	Vs	RTB1	34.5
22	CryIA(c)	Vs	RTB1	34.9

Cry1A(b) 1-2062
Cry1A(c) 1-2062

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